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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,494	02/27/2004	Kozo Tsubouchi	OPS Case 635	7999

23474 7590 12/29/2005

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,494	TSUBOUCHI ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The restriction requirement set forth in the Office action mailed August 31, 2005 is withdrawn. Claims 1-15 have been examined on the merits in their entirety.

2. The Sequence Listing filed January 27, 2005 is approved.

3. The substitute specification filed August 20, 2004 has been entered.

The disclosure is objected to because of the following informalities: SEQ ID NOS need to be inserted after every amino acid and nucleotide sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d). Appropriate correction is required.

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the term "excellent" in claims 1 and 3-5 is unclear. The term "excellent" is a relative term, but no standard of reference is given with which to determine whether or not a peptide composition has "excellent" cell growth promoting activity rather than, e.g., "good" or "poor" cell growth promoting activity. The term is not defined either in the specification or the art. The meaning of the phrase "having specific amino acid sequences" at claim 1, line 6, is not clear. Any given peptide will have a single specific amino acid sequence, and therefore the phrase seems to be reciting an inherent property of any peptide.

5. Claims 2, 3, 7, 9, 11, 13, and 15 are objected to because of the following informalities: SEQ ID NOS need to be inserted after each of the amino acid sequences recited in claims 2 and 3. See 37 CFR 1.821(d). Claims 2 and 3 do not end with periods. Appropriate correction is required.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 6, 8, 10, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hubbell et al (U.S. Patent No. 5,278,063). Hubbell et al teach cell culture substrates comprising the tetrapeptides GRGD. The tetrapeptides promote cell adhesion. See, e.g., the Abstract and the claims. The tetrapeptide GRGD corresponds to a partial peptide of a non-crystalline portion of fibroin from Antheraea yamamai (see the amino acid sequence recited at page 14 of Applicants' specification, second-to-last line, residues 6-9). In view of the similarity in amino acid sequence and utility between the tetrapeptide of Hubbell et al and Applicants' claimed peptide compositions, the former is deemed inherently to be "excellent for promoting cell growth" to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the tetrapeptide of Hubbell et al and Applicants' claimed peptide compositions to shift the burden to Applicants to provide evidence that the claimed peptide compositions are unobviously different than that of Hubbell et al. While the tetrapeptide of Hubbell et al is not actually produced from a silk protein reactant, methods of making do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art. With respect to instant claims 10 and 12, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

8. Claims 1, 6, 8, 10, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (U.S. Patent No. 5,763,399). Lee teaches a composition for revitalizing scar tissue which comprises an angiogenic peptide GRGD. See, e.g., the Abstract and column 6, lines 8-11. The peptide GRGD corresponds to a partial peptide of a non-crystalline portion of fibroin from Antheraea yamamai (see the amino acid sequence recited at page 22 of Applicants' substitute specification, line 8, residues 6-9). In view of the similarity in amino acid sequence and utility between the peptide of Lee and Applicants' claimed peptide compositions, the former is deemed inherently to be "excellent for promoting cell growth" to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of Lee and Applicants' claimed peptide compositions to shift the burden to Applicants to provide evidence that the claimed peptide compositions are unobviously different than that of Lee. While the peptide of Lee is not actually produced from a silk protein reactant, methods of making do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art. With respect to instant claims 8 and 14, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

9. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by the Japanese Patent Application 6-292595. The Japanese Patent Application '595 teaches subjecting silk protein from a domestic silkworm (see paragraph [0014] of the machine translation) to hydrolysis with a protease (see paragraph [0015] of the machine translation) followed by gel filtration (see paragraph [0027] of the machine translation), which is a species of molecular weight fractionation. Applicants' claim recitation "excellent for promoting cell growth" is either

an inherent property of the product or an intended use limitation, and as such does not impart patentability to the method of making claims.

10. Claims 1-15 are rejected under 35 U.S.C. 102(a) as being anticipated by the Yamada et al article (Biomaterials, Vol. 25, Issue 3, pages 467-472). The Yamada et al article teaches peptides derived from the amorphous fraction of chymotrypsin-digested fibroin. The amorphous fraction is further subjected to chromatographic fractionation. The peptides have amino acid sequences corresponding to Applicants' SEQ ID NOS:1 and 2, and enhance the proliferation of cultured human skin fibroblasts. See, e.g., the Abstract; section 2; and section 4. With respect to instant claims 8-13, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

The Scientific and Technical Information Center contacted the publisher of Biomaterials and was informed that the Yamada et al article was made available to the public online in August 2003. Also, the University of Virginia Health Sciences Library has a date stamp on the above issue of December 2, 2003. Accordingly, the Yamada et al article available as prior art against the instant claims under 35 U.S.C. 102(a).

11. Claims 1, 6, 8, 10, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hummel et al (U.S. Patent No. 6,037,158). Hummel et al teach an isolated peptide fragment of alcohol dehydrogenase. The peptide fragment consists of 16 amino acids, and comprises the partial sequence DGGY, which corresponds to residues 7-10 of Applicants' SEQ ID NO:8. See Example 4. In view of Applicants' "comprising" and "having" language, Applicants' claimed peptide compositions are interpreted as permitting the presence of amino acids in addition to those present in peptide chains which form noncrystalline portions of silk proteins. In view of

the similarity in amino acid sequence between the peptide of Hummel et al and Applicants' claimed peptide compositions, the former are deemed inherently to have cell growth promoting properties to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the isolated peptide fragment of Hummel et al and Applicants' claimed products to shift the burden to Applicants to provide evidence that the claimed products are unobviously different than that of Hummel et al. With respect to claims 6, 8, 10, 12, and 14, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

12. Claims 1-3 and 6-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman et al (U.S. Patent Application Publication 2005/0089552). Altman et al teach Bombyx mori silk fibroin isolated from sericin. See paragraph [0087]. In view of Applicants' "comprising" and "having" language, Applicants' claimed peptide compositions and claimed peptides are interpreted as permitting the presence of amino acids in addition to those present in peptide chains which form noncrystalline portions of silk proteins. Because the isolated silk fibroin of Altman et al is the same source from which Applicants derive their partial peptides and peptide chains, inherently the isolated silk fibroin of Altman et al will comprise the same partial peptides and peptide chains having the same amino acid sequences as are claimed by Applicants and inherently will have cell growth promoting properties to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the isolated silk fibroin of Altman et al and Applicants' claimed peptide compositions and peptides to shift the burden to Applicants to provide evidence that the claimed products are unobviously different than that of

Altman et al. With respect to claims 6-15, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

13. The following claim would be novel and unobvious over the prior art of record or any combination thereof:

A peptide consisting of up to forty amino acid residues and comprising an amino acid sequence selected from the group consisting of SEQ ID NOS:3-8.

With the length limitation, the claim distinguishes over intact silk fibroin, intact silk fibroin heavy chain, and intact silk fibroin light chain. Further, the prior art of record does not teach or suggest forming silk fibroin fragments comprising the specific amino acid sequences identified in the above suggested claim. [With respect to SEQ ID NOS:1 and 2, it will first be necessary for Applicants to overcome the Yamada et al article (Biomaterials, Vol. 25, Issue 3, pages 467-472) before claim language can be suggested.]

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
December 20, 2005